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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/651,150 | 08/30/2000 | Donald Payan | A-65679-1/RMS/DHR | 2755 |

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EXAMINER

SEHARASEYON, JEGATHEESAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 05/06/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/651,150

Applicant(s)

PAYAN, DONALD

Examiner

Jegatheesan Seharaseyon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 9-18 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 26-29 is/are allowed.
- 6) ☒ Claim(s) 9-18 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

2. Applicant's election of Group I, claims 1-18 in Paper No. 20 (12 December 2002) is acknowledged. Applicant did not distinctly and specifically point out any errors in the restriction requirement or traverse the restriction. Thus, the election has been treated as an election without traverse (MPEP§818.03(a)). Applicant has elected to cancel claims 1-8 and 19-25. Applicant has added claims 26-29. Therefore, claims 9-18 and 26-29 are pending.

Drawings

3. The drawings filed on 08/30/00 have been approved by the draftsman.

Priority

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Applicant needs to provide the specific prior application information in the first sentence of the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-18 and 26-29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 9 recites the limitation "said cell" in part (b). There is insufficient antecedent basis for this limitation in the claim. Claims 10-15 and 26-29 are rejected insofar as they depend on claim 9.

5b. Claims 16, 17 and 18 are rejected as being vague and indefinite in the recitation of the term "Toso protein". Applicant should particularly point out and distinctly identify the Toso protein by structural or other identifying characteristics associated with the protein (e.g. amino acid sequence, molecular weight, etc.). Referring to biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is. For example, U.S. Patent No: 6,114,515 refers to the same protein as PIRGL-1. The specification gives no definition of what is intended by "Toso", merely an example of one species. Therefore, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6a. Claims 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. U.S. Patent No. 6,114,115.

The instant invention is directed to a method of modulating apoptosis in a cell by administering to the cell an exogenous compound that binds to a Toso protein. Wu et al. disclose therapeutic methods using PIGRL-1 agonists or antagonists (column 17 line 62 to column 18, line 48). PIGRL-1 appears to be identical to be identical to the "Toso" protein of the instant invention. In addition, it is noted that the phrase "of modulating apoptosis in a cell" in the preamble of claim 16 is not given patentable weight, as the recited active steps are not affected by this language. Therefore, Claims 16-18 of the instant invention are anticipated Wu et al. U.S. Patent No. 6,114,115.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 9-15 and 26-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S.

Patent No. 6,555,314

The instant invention is directed to a method of screening for a bioactive agent capable of modulating the activity of a Toso cell surface receptor.

U.S. Patent No. 6,555,314 claims a method of screening for a bioactive agent capable of modulating the activity of a Toso cell surface receptor in cells. The broad claims generically read on the instant invention, though the patent does not explicitly recite the use of various hematopoietic cells.

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to modify the methods claimed in the patent to screening for a bioactive agent capable of modulating the activity of a Toso cell surface receptor in hematopoietic cells. This is because the allowed patent contemplates pathway specific role anti-apoptotic effects in hematopoietic cells for Toso proteins (column 5 lines 62-65). Furthermore, the examples also teach various lymphocytes. Thus, claims 9-15 and

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26-29 of the instant application are obvious over claims 1-9 of U.S. Patent No.

6,555,314.

8. No claims are allowable over prior art.

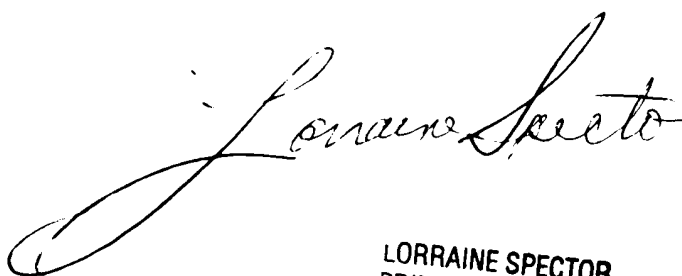
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
May 3, 2003.



**LORRAINE SPECTOR
PRIMARY EXAMINER**